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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,595	12/18/2001	Akane Okada	217484US0	6197

22850 7590 11/24/2003

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT PAPER NUMBER

1616

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,595	OKADA ET AL.	
	Examiner	Art Unit	
	Michael G. Hartley	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

The amendment filed 10/15/2003 has been entered. Claims 1 and 2 have been amended. New claims 3-20 have been added.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 9, 10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Townsend III (US 4,249,412).

Townsend III discloses oral compositions having fluorescein sodium is in the range of 0.025-1.0 %, (which encompasses the claimed range(s), see column 1, lines 50+) and teaches that water is the preferred solvent, see column 2, lines 29+. Townsend III also discloses that the compositions contain a thickening agent, such as, methylcellulose, as claimed, see column 3, lines 3+.

Townsend III fails to disclose the specific concentration range as claimed, but discloses a concentration range that clearly encompasses the claimed range.

It would have been obvious to one of ordinary skill in the art to modify the amount of fluorescein in the solutions disclosed by Townsend III to amounts as encompassed by the claimed range because the patent teaches a range in the amount of fluorescein which may be used to optimize the staining capability of the composition, wherein said range clearly encompasses and overlaps the claimed range. One of ordinary skill in the art would have been motivated to modify the amount of fluorescein as disclosed by the range of claim 1 of the Townsend III patent to take full advantage and/or optimize the invention thereof, which would include an amount within the claimed range(s).

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Claims 1-3 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rueggeberg (US 6,391,281).

Rueggeberg discloses a solution for examination of teeth comprising fluorescein sodium in a solvent, see column 6, lines 20+ and column 7, lines 47+. The amount of fluorescein is preferably in the amount of 0.01 to 0.200%, which clearly encompasses and is within the scope of the claimed range, see column 6, lines 30-35. The solvents include those claimed, e.g., water, etc., see column 7, line 53.

Rueggeberg fails to specifically disclose the concentration range as claimed, but discloses a concentration range that clearly encompasses the claimed range.

It would have been obvious to one of ordinary skill in the art to modify the amount of fluorescein in the solutions disclosed by Rueggeberg to amounts as encompassed by the claimed range because the patent teaches a range in the amount of fluorescein which may be used to optimize the staining capability of the composition, wherein said range clearly encompasses and overlaps the claimed range. One of ordinary skill in the art would have been motivated to modify the amount of fluorescein as disclosed by Rueggeberg to take full advantage and/or optimize the invention thereof, which would include an amount within the claimed range(s).

Claims 7, 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend III (US 4,249,412) as applied to claims 1-6 and 9, 10 and 12-20 above, and further in view of either one of Gaffar (US 4,808,401) and Delli Santi (US 5,945,088).

Townsend III discloses oral compositions having fluorescein sodium, a solvent and a thickening agent, as set forth above.

Townsend III fails to disclose all the same specific thickening agents as claimed or all the same amounts thereof.

However, the use of various thickening agents as equivalents in various amounts is known, as shown by Gaffar and Delli Santi.

Gaffar teaches the use of various thickeners as equivalents, in various amounts, for oral compositions, including those claimed, as well as those disclosed by Townsend III, see columns 5-6.

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Delli Santi teaches the use of various thickeners as equivalents, in various amounts, for oral compositions, including those claimed, as well as those disclosed by Townsend III, see column 5.

It would have been obvious to one of ordinary skill in the art to employ various equivalent thickeners (and in amounts ranges known to be useful) as the thickener in the fluorescein solutions disclosed by Townsend III because the use of various thickeners as equivalents are well known to provide the intended benefit of providing the desired viscosity to the solution for its use as an oral composition, as shown Gaffar and Delli Santi.

Response to Arguments

Applicant's arguments filed 10/15/2003 have been fully considered but they are not persuasive.

Applicant asserts that Townsend III and Rueggeberg fail to disclose a composition containing from 0.04 to 0.3 % by weight of the dye. Applicant's supports this argument by stating that the examples of the patents are not within this range.

This is not found persuasive because both Townsend III and Rueggeberg clearly teach a range that is within the range as claimed. For example, claim 1 of Townsend III states 0.025 to 1 % by weight, which clearly includes the scope of the claimed range. Also, Rueggeberg specifically teaches that the preferred amount is amount of 0.01 to 0.200%, which substantially encompasses the claimed range. The prior art may be relied upon for all that it teaches, and is not limited to examples set forth therein.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH

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shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
11/18/2003